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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/776,350	04/18/97	MACLEAN	A

HM22/0405

EXAMINER

UNGAR, S

ART UNIT

PAPER NUMBER

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DATE MAILED:

04/05/01 *25*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. <b>08/776,350</b>	Applicant(s) <b>MacLean</b>
Examiner <b>Ungar</b>	Group Art Unit <b>1642</b>

Responsive to communication(s) filed on Jan 22, 2001

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 43-58 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 43-58 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. The Amendment filed January 22, 2001 (Paper No.24) in response to the Office Action of September 22, 2000 (Paper No. 23) is acknowledged and has been entered. Previously pending claims 43 and 52 have been amended. Claims 43-58 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. It is noted that the amendment to the specification at page 4, lines 1-6 has not been entered because it is not in compliance. As previously disclosed, the amendment to the specification must be accompanied by an affidavit or declaration executed by applicant or a practitioner representing the applicant stating that the amendatory material consists of the same material incorporated by reference in the referencing application. Neither a declaration nor an affidavit has been received. Further, it is noted that WO92/13943 at page 26 specifically states that strains 1716 have been deposited and that two 1716 strains have been deposited with two different accession numbers. Clarification is required, since the amendment to the specification only recites a single accession number and it is not clear that this is the 1716 strain claimed in the instant specification.

4. The following rejections are being maintained:

***Claim Rejections - 35 USC § 112***

5. Claims 43-50 and 52-57 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 23, Section 5, pages 3-5 and Paper No. 21, Section 5, pages 2-4.

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Applicant argues that (a) the pending claims do not cover a whole universe of mutants since the class of mutants is clearly defined and fully supported by the specification and the incorporation of the text of US Patent No. 6,040,169, as well as by prior art references, thus it is clear that a high level of skill already existed in the art, (b) the present inventors have provided a novel method of treatment of cancers using a specific known class of HSV-1 mutants which at the filing date of the present application were thought not to have the properties required to allow this treatment to be successful, (c) clarification is requested as to why administration of mutant 1716 is enabled while administration of other mutants in the same class is not as per Paper No. 21, page 4, (d) all mutants covered by the present invention, by definition, have the same therapeutic properties thus if one is enabled all are enabled, (e) claim 43 recites a step of infecting the actual tumour cells of the tumour..

The arguments have been considered but have not been found persuasive because (a') the pending claims cover a whole universe of HSV-1 mutants since as previously disclosed, the mutations as claimed are unlimited and can be made in any portion of the HSV-1 and the effects of these mutations on virus function are not predictable and further, as previously disclosed, other than providing a description of the very specific mutations within gamma 34.5 in the long repeat region of HSV-1, the instant specification does not disclose a general principle upon which the instant invention is based and the mutations presented in the instant application to enable the scope of the invention cannot be extrapolated to the broadly claimed mutant herpes simplex virus-1 claimed, further the additional example provided by

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the prior art HSV-1 mutant is not commensurate in scope with the currently claimed mutants which are unlimited and can be made in any portion of the HSV-1. Finally, the information to be incorporated in the text of US Patent No. 6,040,169 is drawn only to the deposit of the claimed 1716 strain, (b') the method of treatment is not novel for the reasons set forth drawn to the rejection of the claims under 35 USC 103, (c') Applicant is referred to the new grounds of rejection recited in Paper No. 23, Section 8, page 9. In response to Applicant's questions, claims 51 and 58 were rejected for the reasons previously set forth in Paper No. 21, Section 6, page 4. The rejections are maintained for the reasons of record, (d') the broadly claimed mutants are rejected for the reasons of record, (e') although the claims now recite a step of infecting the actual tumour cells of the tumour, this does not obviate the instant rejection because the specification does not teach how to make the invention as claimed for the reasons previously set forth since it cannot be predicted that even if the virus infects and replicates within the tumour cells of the tumor whether the replication will be sufficient to produce an effective method of treating.

Applicant's arguments have not been found persuasive and the rejection is maintained.

6. Claims 51 and 58 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 21, Section 7, pages 6-8 and in Paper No. 23, Section 6, page 5.

Applicant states that a copy of the deposit receipt for mutant 1716 has been submitted and the specification has been amended to include this information and that beyond the statements made on page 11 of the Amendment of July 3, in this

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regard, the deposit will be replaced if viable samples cannot be dispensed by the depository. The argument has been considered but has not been found persuasive because Applicant has not complied with the Deposit requirements as set down in Paper No. 21, on pages 6-7. Further, the issue raised drawn to the amendment of the specification and the differences in deposit statements between the world patent and the instant patent must be clarified. For Applicant's convenience, the requirements previously stated are reiterated as follows:

"Applicant has not disclosed the deposit of mutant virus strain 1716. If a deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications. Applicant's provision of these assurances would obviate this objection/rejection.

Affidavits and declarations, such as those under 37 C.F.R. § 1.131 and 37 C.F.R. § 1.132, filed during prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit, the applicant should make the remarks of record in the later application and include a copy of the original affidavit filed in the parent application

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for

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completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of the deposit."

Applicant's arguments have not been found persuasive and the rejection is maintained.

***Claim Rejections - 35 USC § 103***

7. Claims 43-58 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 21, Section 8, pages 8-10, and Paper No. 23, Section 7, pages 5-6.

Applicant argues that (a) in order for an invention to be obvious over the prior art there must be some suggestion or motivation, either in the cited references or in the knowledge generally available to one of ordinary skill in the art to modify the references, there must be a reasonable expectation of success and the prior art reference must teach or suggest all of the claim limitations, (b) without further evidence, the suggestion in the patented reference would not have a reasonable expectation of success because at the time the application was filed, it was believed that HSV-1 inhabits cells of the nervous system, however, the patent contains a suggestion that goes against the current thinking and would have required serious evidence in support before the ordinarily skilled person would have followed the suggestions with any expectation of success and the other references do not encourage the skilled person to follow this motivation, (c) the successful treatment with the 1716 HSV-1 mutant was unexpected. The arguments have been considered but have not been found persuasive because (a') given the teachings of the prior art, the criteria for a finding of obviousness have been met for the reasons previously set

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forth, (b') Applicant's opinion about the current thinking at the time the invention was made is not persuasive, Applicant is invited to submit objective evidence supporting the opinion, further, the reference patent is enabling for the reasons previously set forth, further, the combined references provide both suggestion and motivation to modify the combined references for the reasons previously set forth, one would have had a reasonable expectation of success in treating melanoma since the primary reference specifically suggests the treatment of melanoma and all of the limitations of the claims are taught in the combined references for the reasons previously set forth (c') given teachings of the combined references, the results were not unexpected for the reasons previously set forth. Applicant's arguments have not been found persuasive and the rejection is maintained.

8. Claims 43-58 remain rejected under 35 USC 112, first paragraph, for the reasons previously set forth in Paper No. 23, Section 8, page 7.

Applicant argues that the rejections are traversed for the reasons noted above. The arguments have been considered but have not been found persuasive for the reasons set forth above. Applicant's arguments have not been found persuasive and the rejection is maintained.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

9. Claims 43-58 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 43-58 are rejected because claims 43 and 52 recite the phrase "do not express the normal product or a functionally equivalent product of said gene". The claims are confusing because it is not clear what a functionally equivalent product of said gene is. For example, is the claim now drawn to the insertion of another gene?

10. All other objections and rejections recited in Paper No. 23 are withdrawn.
11. No claims allowed.
12. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

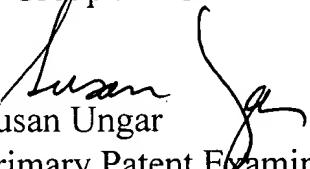
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(703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.

  
Susan Ungar  
Primary Patent Examiner  
April 3, 2001